

REMARKS

Claims 1, 18, 19, 23, 41 and 42 are currently amended;
 Claims 1-16, 18-39, and 41-45 are pending; and
 New claims 46-48 have been added.

Drawings

All drawing sheets are in compliance with 37 CFR 1.121(d).
 "Osteotomy" has been corrected In Figure 11.

Claim Objections

Independent Claims 1 and 23, have been modified so that each of the steps are separated by a line indentation, as per 37 CFR 1.75(i).

Claims 18-19 and 41-42 have been amended as per 35 U.S.C. 112:

Claim 18 depends on claim 1;

Claim 19 depends on claim 18;

Claim 41 depends on claim 23; and

Claim 42 depends on claim 41.

Claim Rejections – 35 USC 102

Examiner Herng-der Day rejected Claims 1-16, 18-39, and 41-45 under 35 USC 102(e), as being anticipated by Krause et al, US Patent No. 6,711,432 B1. Amendments to Claims 1 and 23 have been entered to overcome the Examiner rejections.

Claim 1 Amendements to "Prior To Said Orthopedic Surgical Procedure"

Claim 1 has been been amended to distinguish over Krause et al who teach imaging techniques that require in vivo markers to be surgically affixed to the bone *during surgery*:

"during surgery, radio-opaque multifunctional markers 110 [which have no dimensioning units] are ... attached to the patient's bone as ... a location mechanism" (Krause Column 11, lines 39-40).

Following imaging, the surgeon must wait in the operating room for construction of the 3D model and final calculation of the surgical plan.

Only after 'the new or "final" surgical plan is calculated in the surgical amphitheater as part of the anticipated surgical procedure, the surgeon is ready to actually perform' the surgery (Krause Column 13 lines 5-8).

All of the above steps comprise a *tremendous* time burden on the surgeon in a fully equipped and staffed operating room, adding significant intra-operative expenses to the cost of the procedure

In distinct contrast, Claim 1 of the instant invention claims an imaging system that is obtained and calibrated prior to the surgery, comprising the steps of:

- "b. obtaining and displaying the medical images of the anatomical structure along with said real dimension unit *prior to said orthopedic surgical procedure*; [and]
- c. segmenting the anatomical structure into segments in said medical images *prior to said orthopedic surgical procedure*."

(Instant Application Claim 1)

Support for the amendments to Claim 1 is found, inter alia, in the preamble of Claim 1 of the instant application:

"A method for preoperative planning and simulating of an orthopedic surgical procedure *to be performed* on an anatomical structure..."

Claims 1 and 2 Amendments to "A Structure Defining A Unit Of Dimension Unit"

Returning to our analysis of Krause et al, the markers serve as fiduciary guides for lining up images. The markers do not provide any measurement of the anatomical structure as the markers do not include dimensions as noted above. As a result of being undimensioned markers, special attention to aligning the axes of the imaged object is required:

'In attaching the multifunctional markers to the patient's bone, it is preferable to align the axes through the top of the markers ... [so] the markers are "in the same plane" (Krause Column 11, line 66 to Column 12 line 4).

To provide further alignment of the markers,

"a translucent calibration grid 170 ... [is] mounted ... parallel to the image plane of a lateral and AP ... image." (Krause Column 12, lines 17-23).

Due to the imprecise placement of the markers which are surgically placed within the imaged tissue next to the bone, it may be required that "the pre-surgical plan ... be updated to correct the inherent errors in placing the markers by hand during surgery". (Krause Column 13 lines 1-3)

In distinct contrast, Method Claim 1 of the instant applications defines a method of:

- "a. providing a real dimension unit defining a length, to appear in an image with said anatomical structure for providing calibration of the imaged anatomical structure; [and]
- b. obtaining and displaying the medical images of the anatomical structure along with said real dimension unit."

Furthermore, and in distinct contrast, Apparatus Claim 23 of the instant invention provides an apparatus comprising;

- "a. a real dimension unit defining a length, to appear in an image with said anatomical structure for providing calibration of the imaged anatomical structure; [and]
- b. segmenting means for defining and marking anatomical structure segments in the medical images of the anatomical structure."

Support for the above-noted amendments of Claims 1 and 23 is found on page 10, lines 29-30:

"a real dimension unit in the image [comprising] an object of a known length [is placed next to] the imaged subject".

Amended claims 1 and 23 are clearly novel and inventive and thus allowable over the prior art of Krause et al thereby rendering all claims allowable that depend on claims 1 and 23.

Drawing and Claim objections have been overcome as noted above.

An early Notice of Allowance is respectfully requested.

Respectfully submitted,



Martin Moynihan

Registration No. 40,338

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Enclosures:

- Petition for Extension (1 Month)
- Request for Continued Examination
- Letter To Chief Draftsman;
- 1 Sheet Of Annotated Marked-Up Drawing;
- Formal Drawing Transmittal Sheet;
- 12 Sheets Of Replacement Drawings.



Fig. 11

